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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,096	05/02/2006	Rosario Lizio	28276US0PCT	7191
22850	7590	02/17/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
WINTERBERG, NISSA M				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
02/17/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/564,096	Applicant(s) LIZIO ET AL.
Examiner Nissa M. Westerberg	Art Unit 1618

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see below. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 3, 4, 6 - 10, 33 - 35.
Claim(s) withdrawn from consideration: 2, 5, 11 - 32.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See below.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Nissa M Westerberg/
Examiner, Art Unit 1618

The information disclosure statement filed November 7, 2008 fails to comply with 37 CFR 1.97(d) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

The provisionally double patenting rejection over the copending US Application is 12/030377 is WITHDRAWN.

The rejection of claim 33 under 35 USC 112 first paragraph for new matter is MAINTAINED for the reasons of record set forth in the Office Action mailed October 29, 2008 and those set forth below. Merely because an example fails to include a specific ingredient, in this particular case gelatin, is not sufficient to support the idea that at the time of filing Applicant contemplated compositions which did not include gelatin. This ingredient is not mentioned in the specification as a possible ingredient which may be included, so that exclusion of this ingredient was not contemplated at the time of filing and this rejection is MAINTAINED.

The rejection of claim 34 under 35 USC 112, first paragraph is WITHDRAWN.

The rejection of 35 under 35 USC 122 second paragraph is WITHDRAWN due to the amendments to the claims.

The rejection of claims 1, 3, 6 - 8, 10 and 11 under 35 USC 103(a) as being unpatentable over Watts et al. (US 6,465,626) is MAINTAINED for the reasons of record set forth in the Office Action mailed October 29, 2008 and those set forth below. Applicant reiterates that the gelatin of the cited prior art is bioadhesive but not mucoadhesive. Applicant has not provided evidence that the compositions do not meet the mucoadhesive effect as recited in the instant claims. As explained in greater detail in the previous office Action, in the absence of a definition in the claims and/or specification, "consisting essentially of" will be interpreted as equivalent to comprising, so the relative amounts of the chitosan and gelatin in the cited prior art are not relevant. Because of the open language of "comprising" used in the preamble, the pharmaceutical forms of the instant claim do not exclude those compositions which also contain a bioadhesive agent and therefore have both mucoadhesive and bioadhesive properties.

The rejection of claims 1 and 4 under 35 USC 103(a) as being unpatentable over Watts et al. further in view of Berliner et al. (US 5,849,327) is MAINTAINED for the reasons of record set forth in the Office Action mailed October 29, 2008 and those set forth below. As the arguments presented in regards to the primary reference of Watts et al. were not persuasive as discussed above, and Applicant has presented no substantive arguments in regards to Berliner et al., this rejection is MAINTAINED.

The rejection of claims 1, 9 and 10 under 35 USC 103(a) as being unpatentable over Watts et al. further in view of Engel et al. (US 5,773,032) is MAINTAINED for the reasons of record set forth in the Office Action mailed October 29, 2008 and those set forth below. As the arguments presented in regards to the primary reference of Watts et al. were not persuasive as discussed above, and Applicant has presented no substantive arguments in regards to Engel et al., this rejection is MAINTAINED.

The rejection of claim 34 under 35 USC 102(b) as being anticipated by Shimono et al. (EP 1203590) is MAINTAINED for the reasons of record set forth in the Office Action mailed October 29, 2008 and those set forth below. Applicant traverses this rejection on the grounds that claim 34 as it reads on the elected species, does not anticipate because it does not disclose centrorrellix, that the dissolution of the enteric coating of the prior art will take "a long time to dissolve" and the water insoluble polymer layer with the chitosan particles separate the non-poreil layer from the outer enteric coating layer, and therefore the prior art does not meet the limitation of not having a layer separating the inner matrix from the outer coating. Finally, the chitosan particles in Shimono are not a mucoadhesive component but rather are taught as pore foaming agents. These arguments are not persuasive. Claim 34 is not specifically limited to the elected species. Applicant has not presented any evidence, only arguments, the layer does not dissolve under the conditions recited in the instant claims and a complete dissolution of the layer is not required by the instant claims. The claim uses the open language so addition layers beyond those recited are not excluded and the inner matrix layer need not be the innermost layer. The water insoluble polymer layer with the chitosan reads on the inner matrix layer, and in the cited prior art, there is no intervening layer between this inner matrix layer and the outer enteric coating. The properties of a material cannot be separated from the material itself, and while Shimono et al. may describe the chitosan as a pore forming agent, chitosan is also mucoadhesive and therefore the limitations of the instant claim are all recited by the cited prior art.

The rejection of claims 1 and 33 as being unpatentable under 35 USC 103(a) as being unpatentable over Shimono et al. in view of Watts et al. MAINTAINED for the reasons of record set forth in the Office Action mailed October 29, 2008 and those set forth below. Applicant has presented no additional arguments in regards to Shimono et al. and Watts et al. beyond those discussed above that were not persuasive, this rejection is MAINTAINED..